IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8436

Bartle, C.J.

March 18, 2010

Brenda J. Spiker ("Ms. Spiker" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Douglas A. Spiker, Ms. Spiker's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Allan L. Klein, M.D., F.R.C.P.(C), F.A.C.C., F.A.H.A., F.A.S.E. Based on an echocardiogram dated March 4, 1998, Dr. Klein attested in Part II of Ms. Spiker's Green Form that she suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin®

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3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

and/or Redux™.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $855,717.[5]

Dr. Klein also attested that Ms. Spiker did not have moderate or greater mitral regurgitation confirmed by echocardiogram prior to taking Pondimin® and/or Redux™. Under the Settlement Agreement, a diagnosis of FDA Positive[6] regurgitation confirmed by echocardiogram prior to the ingestion of Diet Drugs for the valve that is the basis of the claim requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)iii)c).[7] As the Trust does not

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4. Dr. Klein also attested that claimant suffered from mild aortic regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

6. For purposes of the mitral valve, FDA Positive is defined as "[m]oderate or greater regurgitation, defined as regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22.

7. Dr. Klein also attested that claimant did not have a diagnosis of Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition, which also requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)iii)d). Given our resolution regarding the presence of moderate or greater mitral regurgitation confirmed by echocardiogram prior to the ingestion of Diet Drugs, we need not address the additional reduction

(continued...)

contest Ms. Spiker's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In April, 2005, the Trust forwarded the claim for review by Ioannis P. Panidis, M.D., F.A.C.C., one of its auditing cardiologists.[8] In audit, Dr. Panidis concluded that there was no reasonable medical basis for Dr. Klein's finding that claimant did not have moderate or greater mitral regurgitation confirmed by echocardiogram prior to taking Pondimin® or Redux™. In support of his conclusion, Dr. Panidis explained that:

> Although differing dates of "Fen-Phen" use were noted in the medical records, patient stated in the BLUE FORM[9] - page 4 that she used Pondimin in EARLY 1997; moderate or greater mitral regurgitation was documented by echocardiograms prior to that date.

Based on the auditing cardiologist's finding that claimant had moderate or greater mitral regurgitation prior to the ingestion of Diet Drugs, the Trust issued a post-audit determination that Ms. Spiker was entitled only to Matrix B-1,

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7. (...continued)
factor of Systemic Lupus Erythematosus and valvular abnormalities of a type associated with this condition.

8. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims are subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Matrix A-1, Level III claim, pursuant to the ¶, the Trust audited Ms. Spiker's claim.

9. Under the Settlement Agreement, the Blue Form is one of the forms used by claimants to submit claims and register for benefits under the Settlement Agreement. See Settlement Agreement § VI.C.2.a.

Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[10] In contest, claimant argued that she is entitled to Matrix A-1 benefits because Dr. Panidis did not opine that Ms. Spiker suffered from moderate or greater mitral regurgitation prior to May 1, 1996.[11] In addition, claimant submitted a letter from Dr. Klein, in which he stated, in relevant part, that:

> I have reviewed the medical records of Brenda Spiker including the actual transesophageal echocardiogram performed at the Cleveland Clinic of [sic] 3/17/1998 .... It is my opinion that the appearance of the mitral valve at the time of surgery is classic for anorexigenic induced valvular heart disease. In this setting, the mitral valve leaflets were thickened, curled at the edges, showing decreased mobility and without commissural fusion (4+ MR). In addition, there were similar findings for the aortic valve (1-2+ AR). In fact, her echocardiogram has been used as a teaching case of anorexigenic induced valvular heart disease shown worldwide. Thus, I do strongly dispute the findings of the auditing cardiologist.

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10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Spiker's claim.

11. Ms. Spiker submitted records from CVS Pharmacy and Dr. Bob Medical Weight Loss Center, which, according to claimant, establish that she ingested Diet Drugs beginning in May 1996, not early 1997 as indicated in her Blue Form. For purposes of resolving this claim, we will accept May 1, 1996 as the earliest date on which Ms. Spiker ingested Diet Drugs.

> In the patient's records, there is a varying report of when the diet pills were taken. In the records that were available, I did not note an echocardiogram showing moderate or greater mitral regurgitation present prior to anorexigenic usage. According to the records at The Cleveland Clinic Foundation and Doctor Evans, the patient used Fen-Phen from 1995 or 1996. In Doctor Evans' 11/3/1997 office note, the patient was being treated for pericardial effusion and acute pleural pericarditis.

The Trust then issued a final post-audit determination that Ms. Spiker was only entitled to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Spiker's claim should be paid. On December 9, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5886 (Dec. 9, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 27, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a

reasonable medical basis for the attesting physician's finding that she did not have moderate or greater mitral regurgitation confirmed by echocardiogram prior to taking Pondimin® and/or Redux™. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Spiker relies on the letter from Dr. Klein that she submitted in contest, as well as claimant's medical records. In response, the Trust argues that claimant failed to establish a reasonable medical basis for her claim because she has not rebutted any of the medical records that reflect that she had moderate or greater mitral regurgitation confirmed by an echocardiogram prior to her ingestion of Diet Drugs.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. The Settlement Agreement requires that a claim for damage to the mitral valve be reduced to Matrix B-1 if the claimant had "FDA Positive regurgitation (confirmed by Echocardiogram) prior to Pondimin® and/or Redux™ use for the valve that is the basis of [the] claim." Settlement

Agreement § IV.B.2.d.(2)(c)iii)c). As we previously stated, under the Settlement Agreement, "FDA Positive" for purposes of the mitral valve is "[m]oderate or greater regurgitation, defined as regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Id. § I.22. Ms. Spiker's claim for damage to her mitral valve and resulting mitral valve surgery, therefore, must be reduced to Matrix B-1 if there is no reasonable medical basis for the attesting physician's representation that claimant was not diagnosed with moderate or greater mitral regurgitation confirmed by echocardiogram prior to her ingestion of Diet Drugs.

First, and of crucial importance, claimant does not adequately contest the finding of Dr. Panidis that Ms. Spiker was diagnosed with moderate or greater mitral regurgitation prior to her ingestion of Diet Drugs. Although claimant submitted a letter from Dr. Klein wherein he states that he "did not note an echocardiogram showing moderate or greater mitral regurgitation present prior to anorexigenic usage," Ms. Spiker's medical records contain three echocardiogram reports that reflect that she had moderate or greater mitral regurgitation prior to May 1, 1996, the date she first ingested Diet Drugs.

Specifically, in a report for an April 12, 1995 echocardiogram, the reviewing cardiologist, Rod A. Wall, M.D., F.A.C.C., concluded that claimant's "[m]itral valve reveals 2-3+ mitral regurgitation." Dr. Wall also observed that Ms. Spiker had "[p]robable myxomatous mitral valve disease with moderate to

severe mitral insufficiency; 2-3+ mitral regurgitation." In a subsequent report for an April 17, 1995 echocardiogram, the reviewing cardiologist, Charles J. Oschwald, M.D., stated the following conclusions regarding claimant's mitral regurgitation:

> Mitral regurgitation = 4+
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> * * *
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> 1. Severe mitral valve disease (suspect congenital type with myxomatous involvement):
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> a. Severe holosystolic mitral valve insufficiency. The regurgitant mitral jet is a wide jet and traverses the entire length of the left atrium and is more of a laterally displaced jet. This jet appears to penetrate the pulmonary vein region. This is consistent with severe mitral valve insufficiency.
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> * * *
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> COMMENT:
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> When compared to prior echodoppler of 4/12/95, there is now progressive, severe mitral valve insufficiency requiring clinical correlation. Long term, this patient's degree of mitral valve insufficiency will ultimately lead to adverse remodeling of the left ventricle.

Additionally, in a report for a May 31, 1995 echocardiogram, Dr. Wall stated the following regarding claimant's mitral regurgitation:

> Brief Cardiac History: The patient has a h/o known mitral valvular insufficiency and a pericardial effusion. Echo is performed to re-assess left ventricular function, degree of mitral insufficiency and to re-assess degree of prior pericardial effusion.

* * *

DOPPLER/ECHOCARDIOGRAM/COLOR FLOW

I. Mitral valve--4+ MR with a centrally directed jet which reaches the level of the pulmonic veins.

* * *

CONCLUSION:

* * *

2. Severe mitral insufficiency (4+ MR) and the mitral valve is suggestive of a cleft anterior mitral leaflet with myxomatous changes of the anterior and posterior leaflet.

Despite the opportunity to do so, claimant did not address any of these echocardiogram reports in her show cause submissions. On this basis alone, claimant has failed to establish a reasonable medical basis for her attesting physician's finding that she did not have moderate or greater mitral regurgitation confirmed by an echocardiogram prior to her ingestion of Diet Drugs.

We also reject claimant's argument that she is entitled to Matrix A-1 benefits based on the opinion of Dr. Klein that "the appearance of the mitral valve at the time of surgery is classic for anorexigenic induced valvular heart disease."[12] Causation is not at issue in resolving Ms. Spiker's claim for Matrix Benefits. Rather, claimant is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

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12. Dr. Klein also does not address the echocardiogram reports of April 12, 2009, April 17, 1995, and May 31, 1995.

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred ....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation or valve replacement at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if claimant is diagnosed as FDA Positive confirmed by echocardiogram prior to ingestion of Diet Drugs for the valve that is the basis of the claim. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion that her mitral regurgitation and resulting mitral valve surgery were caused by her ingestion of Diet Drugs is irrelevant to the issue before the court.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have moderate or greater mitral regurgitation confirmed by echocardiogram prior to

her ingestion of Diet Drugs. Therefore, we will affirm the Trust's denial of Ms. Spiker's claim for Matrix A-1 benefits and the related derivative claim submitted by her spouse.